

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION)	
)	MDL NO. 1203
)	
THIS DOCUMENT RELATES TO:)	
)	
SHEILA BROWN, et al.)	
)	CIVIL ACTION NO. 99-20593
v.)	
)	
AMERICAN HOME PRODUCTS CORPORATION)	2:16 MD 1203
)	

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8489

Bartle, C.J.

June 30, 2010

The Estate of Anne Morris ("Estate"), a representative claimant under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether the Estate has demonstrated a reasonable medical basis to support its claim for Matrix Compensation Benefits ("Matrix Benefits").²

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify for compensation purposes Diet Drug Recipients based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to the Diet Drug Recipient's

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To seek Matrix Benefits, a representative claimant³ must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The representative claimant completes Part I of the Green Form. Part II is completed by an attesting physician who must answer a series of questions concerning the deceased's medical conditions that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, if the representative claimant is represented by an attorney, the attorney must complete Part III.

In July, 2001, William Marcus Morris and James Henry Morris, co-executors of the Estate of Anne Morris, submitted a completed Green Form to the Trust signed by the attesting physician, James S. Gainer, Jr., M.D. Based on an echocardiogram dated February 12, 1998, Dr. Gainer attested in Part II of the Green Form that Ms. Morris suffered from moderate aortic

2. (...continued)
valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to representative claimants where the Diet Drug Recipients are diagnosed with serious VHD, they took the drugs for 61 days or longer, and they did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to representative claimants where the Diet Drug Recipients were registered as having only mild mitral regurgitation by the close of the Screening Period, they took the drugs for 60 days or less, or they were diagnosed with conditions that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. Under the Settlement Agreement, representative claimants include estates, administrators or other legal representatives, heirs or beneficiaries. See Settlement Agreement § II.B.

regurgitation, surgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™, and death resulting from a condition caused by VHD or valvular repair/replacement surgery.⁴ Based on such findings, the Estate would be entitled to Matrix A-1, Level V benefits in the amount of \$1,024,981.⁵

In the report of the echocardiogram, the reviewing cardiologist noted that there were "mildly calcified aortic cusps with a valve area and peak velocity c/w mild AS." Dr. Gainer, however, attested in the Green Form that Ms. Morris did not suffer from aortic sclerosis. Under the Settlement Agreement, the presence of aortic sclerosis in Diet Drug Recipients who were sixty (60) years of age or older at the time they were first diagnosed as FDA positive requires the payment of reduced Matrix

4. Dr. Gainer also attested that Ms. Morris suffered from mild or greater aortic regurgitation and/or moderate or greater mitral regurgitation with bacterial endocarditis, pulmonary hypertension secondary to severe aortic regurgitation, an abnormal left ventricular end-systolic dimension, a reduced ejection fraction in the range of 50% to 60%, and New York Heart Association Functional Class III and IV symptoms. These conditions, however, are not at issue in this claim.

5. Under the Settlement Agreement, a claimant or representative claimant is entitled to Level V Matrix Benefits if the Diet Drug Recipient suffered "[d]eath resulting from a condition caused by valvular heart disease or valvular repair/replacement surgery which occurred post-Pondimin® and/or Redux™ use supported by a statement from the attending Board-Certified Cardiothoracic Surgeon or Board-Certified Cardiologist, supported by medical records." Settlement Agreement § IV.B.2.c.(5)(c).

Benefits.⁶ See Settlement Agreement § IV.B.2.d.(2)(c)i)c). As the Trust does not contest the Estate's entitlement to Level V benefits, the only issue before us is whether the Estate is entitled to payment on Matrix A-1 or Matrix B-1.

In December, 2003, the Trust forwarded the claim for review by Michael A. Rihner, M.D., one of its auditing cardiologists. In audit, Dr. Rihner concluded that there was no reasonable medical basis for Dr. Gainer's finding that Ms. Morris did not have aortic sclerosis, noting that "[t]he aortic valve appeared sclerotic."

Based on the auditing cardiologist's finding that Ms. Morris had aortic sclerosis, the Trust issued a post-audit determination that the Estate was entitled only to Matrix B-1, Level V benefits. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), the Estate contested this adverse determination.⁷ In contest, the Estate submitted a statement from Robert E. Jones, M.D., the surgeon who performed decedent's aortic valve replacement. Dr. Jones stated that he "did not observe nor palpate stiffness of the valve suggestive of

6. FDA Positive is defined, in pertinent part, as "mild or greater regurgitation of the aortic valve...." Settlement Agreement § I.22.a.

7. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to the Estate's claim.

pathologic aortic sclerosis." Dr. Jones also opined that decedent's aortic valve replacement surgery was required as a result of Diet Drug ingestion by Ms. Morris.

The Trust then issued a final post-audit determination, again determining that the Estate was entitled only to Matrix B-1, Level V benefits. The Estate disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rules 18(c). The Trust then applied to the court for issuance of an Order to show cause why the Estate's claim should be paid. On August 9, 2004, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 3817 (Aug. 9, 2004).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. The Estate then served a response upon the Special Master. The Trust submitted a reply on December 7, 2004, and the Estate submitted a sur-reply on December 20, 2004. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor⁸ to review claims after the Trust and

8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a
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the Estate have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and the Estate and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether the Estate has met its burden in proving that there is a reasonable medical basis for the attesting physician's finding that Ms. Morris did not have aortic sclerosis at the time she was first diagnosed as FDA Positive. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in the Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of its claim, the Estate argues that there is a reasonable medical basis for Dr. Gainer's Green Form representation that Ms. Morris did not have aortic sclerosis at

8. (...continued)

Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

the time she was first diagnosed as FDA positive because he is well-qualified and untainted by a history of providing expert opinions on behalf of claimants. In addition, the Estate argues that Dr. Jones, the surgeon who performed decedent's aortic valve replacement, is in the best position to opine on the presence of aortic sclerosis because he is the only physician to have personally examined decedent's heart valve. In his supplemental statement, Dr. Jones explained that:

During my surgery I did excise a moderate amount of calcium along the free edge of the leaflets back to the annulus, and I performed annular decalcification during the procedure, as well. However, I did not observe a sufficient amount of calcium in this area, or elsewhere, that would suggest to me that Mrs. Morris had aortic sclerosis on February 12, 1998.

* * *

The lack of **pathologic** aortic sclerosis simply means that the extent of sclerosis present at the time of surgery was not the medical cause for the replacement of the valve. I would further add, as indicated in my operative note, that Mrs. Morris had a trileaflet valve. At age sixty-one (in February, 1998), it would be highly unlikely for someone with a trileaflet valve to develop aortic sclerosis due to age.... Moreover, the specific problem leading to Mrs. Morris' need for surgery was a "leaky valve". It has been my experience, and consistent with my education and training, that "leaky valves", like Mrs. Morris', are caused most often by the effects of drugs, not aging. Age and degenerative changes cause stenosis in valves that can ultimately lead to their replacement, but such was not the case with Mrs. Morris.

* * *

It is my opinion to a reasonable degree of medical probability that Mrs. Morris did not have aortic sclerosis when she demonstrated mild aortic regurgitation, February 12, 1998....

* * *

While I acknowledge that reasonable physicians can disagree as to their opinion on a particular issue, based upon my training, experience and surgical treatment of Mrs. Morris, the cardiologist who opined that Mrs. Morris did not have aortic sclerosis as of February 12, 1998 certainly has a **reasonable medical basis** for such an opinion.

(Emphasis in original.)

In response, the Trust argues that the Estate has failed to meet its burden of proof because it did not rebut the finding of the auditing cardiologist that the February 12, 1998 echocardiogram demonstrated aortic sclerosis. The Trust also contends that the statement of Dr. Jones conflicts with the reference in the operative notes to calcium, which is associated with aortic sclerosis. The Trust further argues that the amount of aortic sclerosis and whether it caused decedent's regurgitation are irrelevant because the presence of aortic sclerosis, regardless of amount, requires the payment of reduced benefits. Finally, the Trust argues that for claims based on surgery, payment must be reduced to Matrix B-1 when any reduction factor, including aortic sclerosis, is observed at the time of surgery, regardless of when the condition developed.⁹

9. Additionally, the Trust notes that the February 12, 1998
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In its sur-reply, the Estate argues that the Settlement Agreement and the Green Form dictate that the only relevant time for determining the presence of aortic sclerosis is when a Diet Drug Recipient is first diagnosed as FDA Positive after age sixty (60). Thus, according to the Estate, the finding of aortic sclerosis at the time of surgery, which was performed after Ms. Morris was diagnosed as FDA Positive, should not be considered.

The Technical Advisor, Dr. Vigilante, reviewed the February 12, 1998 echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding that Ms. Morris did not have aortic sclerosis. Specifically, Dr. Vigilante stated that:

This study demonstrated obvious and definite sclerosis of the aortic valve. There was significant thickening and calcification of the leaflets particularly the non-coronary leaflet. The other leaflets also were thickened and calcified to a lesser extent. The aortic annulus was also calcified. This aortic sclerosis was manifested by significantly increased echogenicity and reflectance of ultrasound in the area of the aortic leaflets and annulus. Sclerosis of the aortic valve was seen in multiple views.

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echocardiogram report as well as cardiac catheterization reports dated May 14, 1998 and May 5, 2000 note the presence of aortic stenosis, which also is a reduction factor that would require the payment of reduced Matrix Benefits. Given our disposition of this claim, however, we need not address this argument.

[I]t was not reasonable for the [decedent's] surgeon to conclude that, based on his observations at surgery, there was not a sufficient amount of calcium to suggest that [Ms. Morris] had aortic sclerosis when she was initially diagnosed as FDA positive 2 years prior to surgery. Based on Dr. Jones' own operative report, it is obvious that a significant amount of calcium was noted on the aortic valve at the time of surgery on May 5, 2000. It would be impossible for any individual to determine how long the calcium had been present on the aortic valve. In fact, aortic sclerosis usually takes several years to occur.

* * *

[A]ortic sclerosis is a pathologic condition of varying severity from one case to another. There is no such entity as non-pathologic aortic sclerosis.

In response to the Technical Advisor Report, the Estate argues that Dr. Vigilante failed to address the findings of the February 12, 1998 echocardiogram report or the report of the May 14, 1998 cardiac catheterization. The Estate also contends that Dr. Vigilante failed to identify any record of aortic sclerosis prior to the February 12, 1998 echocardiogram, and therefore the aortic sclerosis was caused by the ingestion of Diet Drugs.

After reviewing the entire Show Cause Record, we find the Estate's arguments are without merit. First, and of crucial importance, claimant does not adequately challenge the specific findings of the auditing cardiologist or the Technical Advisor. The Settlement Agreement specifically provides that the presence of aortic sclerosis in Diet Drug Recipients who were sixty (60)

years of age or older at the time they were first diagnosed as FDA Positive requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)i)c).¹⁰ Here, Dr. Rihner specifically concluded after reviewing the February 12, 1998 echocardiogram that decedent's "aortic valve appeared sclerotic." Moreover, Dr. Vigilante reviewed the echocardiogram and determined that it "demonstrated obvious and definite sclerosis of the aortic valve." Dr. Vigilante explained that "[t]here was significant thickening and calcification of the leaflets particularly the non-coronary leaflet.... This aortic sclerosis was manifested by significantly increased echogenicity ... [and] was seen in multiple views." Claimant does not adequately refute or respond to these findings. Instead, she relies on the supplemental statement of Dr. Jones wherein he restates his conclusion that although Ms. Morris had calcification, it did not "suggest" that she had aortic sclerosis at the time she was first diagnosed as FDA Positive. Notably, Dr. Jones did not attempt to rebut or refute the express findings of the auditing cardiologist or the Technical Advisor with respect to their review of the February 12, 1998 echocardiogram. On this basis alone, claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her claim.

10. There is no dispute that Ms. Morris was first diagnosed as FDA Positive after reaching age sixty (60).

In addition, the Estate's reliance upon the opinion of Dr. Jones that this claim should not be reduced to Matrix B-1 because aortic sclerosis was not the medical cause of decedent's aortic regurgitation or valve replacement surgery is misplaced. Causation is not at issue in resolving the applicability of this reduction factor. Rather, the Estate is required to show that it meets the objective criteria set forth in the Settlement Agreement. As we have previously concluded:

Class members do not have to demonstrate that their injuries were caused by ingestion of Pondimin and Redux in order to recover Matrix Compensation Benefits. Rather, the Matrices represent an objective system of compensation whereby claimants need only prove that they meet objective criteria to determine which matrix is applicable, which matrix level they qualify for and the age at which the qualification occurred....

PTO No. 1415 at 51 (Aug. 28, 2000). In addition, we noted that:

... [I]ndividual issues relating to causation, injury and damage also disappear because the settlement's objective criteria provide for an objective scheme of compensation.

Id. at 97. Accordingly, except where specifically required by the Settlement Agreement, claimants or representative claimants are not required to demonstrate causation to prove a claim for Matrix Benefits. Similarly, the Trust does not need to establish that a reduction factor caused the regurgitation or valve replacement at issue. The Settlement Agreement clearly and unequivocally requires a claim to be reduced to Matrix B-1 if any amount of aortic sclerosis is present in a Diet Drug Recipient

that is sixty (60) years of age or older at the time they are first diagnosed as FDA Positive. We must apply the Settlement Agreement as written. Accordingly, the opinion of Dr. Jones that the presence of aortic sclerosis was not the cause of the aortic regurgitation or valve replacement is irrelevant.

For the foregoing reasons, we conclude that the Estate has not met its burden of proving that there is a reasonable medical basis for finding that Ms. Morris did not have aortic sclerosis at the time she was first diagnosed as FDA Positive. Therefore, we will affirm the Trust's denial of the Estate's claim for Matrix A-1 benefits.